FDA 510(k) Premarket Notification

K261826 VSP System (Titanium Palatal Splint)

CLEARED

Jun 3, 2026
2 days to decision

K261826 · Product code: **DZJ** · Dental
Source: https://www.510kdatabase.net/k261826/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Driver, Wire, And Bone Drill, Manual (DZJ)
Date received	Jun 1, 2026
Decision date	Jun 3, 2026
Days to decision	2 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**3D Systems, Inc.**
Location	Golden, CO, US
Contact	Archana Gopalan
Website	http://www.3dsystems.com/
510(k) history	12 submissions · 12 cleared · 2016-2026

3D Systems, Inc. is a healthcare technology company specializing in personalized medical device solutions. The company operates with a manufacturing facility in Golden, Colorado, and serves orthopedic, neurology, and radiology specialties through advanced 3D printing and imaging technologies. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2016. Orthopedic devices represent the dominant category, including ankle and cranial implant systems. The latest clearance in 2025 confirms continued regulatory activity and product in...

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov